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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,322	10/27/2005	Michael Katze	55382-23	5108

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,322	KATZE ET AL.	
	Examiner	Art Unit	
	MISOOK YU	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/07, 6/18/07, 6/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on 04/09/2008 is acknowledged. Applicant argument of claim 16 belong to group I is persuasive, therefore claim 16 is rejoined with group I. Claims 1-6 are pending, and claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-14 and 16 are examined on merits.

Information Disclosure Statement

The information disclosure statement filed 10/08/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No reference is listed in the 1449.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 11-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for serum based immunoassay using anti-PLA2G13 and other art-known techniques (see the art rejection below), does not reasonably provide enablement for assay using a receptor

molecule as recited in claim 3 or HCC imaging using anti- PLA2G13 as recited in claim 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the claimed invention is drawn to an assay using a receptor molecule of PLA2G13 and a method of HCC imaging using anti- PLA2G13 antibody.

The specification on 4 lines 32 discloses that NCBI accession no. NP 115951 is PLA2G13, which is non-cell associated (note page 6 lines 31): a posting filing art, Rouault et al., Oct 7, 2003 vol., 42, issue 39, pages 11494-503 mirrors this disclosure, i.e. PLA2G13 is a secreted protein. Rouault et al., also disclose that the receptor binding to PLA2G13 has not been identified yet. The specification does not teach the identity of a receptor molecule binding to PLA2G13. This suggests that one of skilled in the art has to identify the claimed receptor if it exists.

As for HCC imaging with anti-PLA2G13, the specification on page on page 4 discloses that over-expression of mRNA encoding PLA2G13 is detected on microarray. The specification does not teach whether PLA2G13 protein is overexpressed in liver. However, Smith et al., Cancer Research, 2003 Feb 15;63(4):859-64 teach two secreted phospholipases A2 (PLA2G13 and PLA2G7) may "provide potential HCC serological markers." Note the abstract. This and Rouault et al. above, both indicate that PLA2G13 would be in blood, not liver. The specification does not teach whether one of skill in the art would image liver to detect HCC using antibody to a blood protein. Fan et al (cited below) on page 374 teach "the rationale of radioimmunoimaging" is based on "the principle that a specific, radio-labeled antibody recognizes and binds to a specific, radio-labeled antibody recognizes and binds to a defined tumor-associated antigen and thus to the tumor". Trojan et al (cited below) also teach that in order to image HCC using PET, the liver to be imaged has to uptake the radioactive material.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use the instantly claimed invention, broad breath of the claims, it is concluded that undue experimentation is required to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujiyama et al., filed as IDS but not listed on 1449, Hepato-Gastroenterol, vol 33, 1986, pages 201-205.

Claims 1 and 2 are drawn to method of detecting HCC comprising assaying a non-cell associated protein (serum protein) using ELISA.

Fujiyama et al., teach that plasma PIVKA-11 in HCC patient is elevated. Note the abstract, and Materials and Methods on page 201.

Claims 6-9, 11, 12, and 14 are rejected under 35 U.S.C. **102(b)** as being anticipated by Trojan et al., IDS, The American Journal of Gastroenterology, 1999, vol. 94, pages 3314-19.

Claims 6-9, 11, 12, and 14 are drawn to method of detecting HCC comprising assaying a cell-associated protein in a liver biopsy sample or comprising imaging of liver using a conjugate comprising a target reagent (ligand binding to a HCC cell associated protein) and an imaging agent.

Trojan et al., teach an immunohistochemistry in a liver biopsy sample from HCC using mutant and wild-type p53 protein on page 3315, and also teach HCC imaging using ^{18}F-FDG uptake. Since the glucose binds to the glucose transporter expressed on liver cells in order for the imaging works, the glucose molecule used meet the limitation of ligand in the instant claim 11.

Claims 1, 2, 11, 12, 14, and 16 are rejected under 35 U.S.C. **102(b)** as being anticipated by Fan et al., 1992, J Cancer Res Clin Oncol, vol. 118, pages 371-376.

Claims 1, 2, 11, 12, 14, and 16 are drawn to method of detecting HCC comprising assaying a non-cell associated protein (serum protein) using antibody or comprising imaging of liver using a conjugate comprising a target reagent (antibody) and an imaging agent.

Fan et al., teach that serum alpha-fetoprotein level and HCC is correlated and also teach that radioimmunoimaging of HCC with ^{131}I or ^{125} I-ferritin antibody

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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